Complete Summary

GUIDELINE TITLE

Treatment of primary headache: chronic daily headache. Standards of care for headache diagnosis and treatment.

BIBLIOGRAPHIC SOURCE(S)

Mathew N, Ward T. Treatment of primary headache: chronic daily headache. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 73-80. [4 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the U.S. Food and Drug Administration (FDA) requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the <u>FDA Web site</u> for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA

determines pose a serious and significant public health concern. See the <u>FDA Web</u> site for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Chronic daily headache (CDH) including:

- Chronic tension-type headache
- Chronic migraine (formerly known as transformed migraine with or without analgesia rebound)
- New daily persistent headache
- Chronic cluster headache
- Hemicrania continua
- Chronic paroxysmal hemicrania
- Hypnic headache
- Idiopathic stabbing headache
- SUNCT (short-lasting, unilateral neuralgiform headaches with conjunctival injection and tearing)
- Cranial neuralgias (e.g., trigeminal neuralgia)

GUIDELINE CATEGORY

Diagnosis

Prevention

Treatment

CLINICAL SPECIALTY

Family Practice Internal Medicine Neurology

INTENDED USERS

Health Care Providers Physicians

GUIDELINE OBJECTIVE(S)

- To improve the medical treatment of headache
- To help physicians and other health care professionals to:
 - Rule out secondary headache and establish a primary headache diagnosis
 - Set reasonable goals with each patient, identifying expectations and individual needs by tailoring the educational component to the patient's level of active participation and desire
 - Design a treatment plan, combining nonpharmacologic with pharmacologic approaches as necessary to:
 - Minimize symptomatology
 - Reduce disability
 - Improve quality of life
 - Provide follow-up care for long-term headache management to:
 - Reassess how well the treatment plan is achieving established goals
 - Reevaluate patient needs and specific headache patterns
 - Recognize indications for appropriate and timely referrals to specialists

TARGET POPULATION

Patients with chronic daily headache (CDH)

INTERVENTIONS AND PRACTICES CONSIDERED

General Management Strategies

- 1. Patient education and involvement in treatment plan
- 2. Early consultation with headache specialist
- 3. Screening and counseling patients for medication overuse
- 4. Stopping or tapering medication that is being overused
- 5. Providing measures to cover the withdrawal headache that will ensue upon stopping the overused medication
 - Clonidine (for opioid withdrawal)
 - Temporary substitution of phenobarbital for butalbital (to avoid seizures or other serious withdrawal symptoms)
 - Intravenous (IV) dihydroergotamine (DHE) (for headache relief)

Pharmacologic Treatments

- 1. Acetazolamide
- 2. Amitriptyline
- 3. Botulinum toxin type A
- 4. Divalproex sodium
- 5. Doxepin
- 6. Fluoxetine
- 7. Indomethacin

- 8. Nefazodone
- 9. Phenelzine
- 10. Tizanidine
- 11. Topiramate
- 12. Glucocorticoids, including dexamethasone, prednisone, methylprednisolone
- 13. Dihydroergotamine
- 14. Caffeine
- 15. Codeine
- 16. Oxycodone
- 17. Butalbital
- 18. Propoxyphene
- 19. Butorphanol
- 20. Ergotamine tartrate
- 21. Almotriptan
- 22. Eletriptan
- 23. Sumatriptan succinate
- 24. Naratriptan
- 25. Rizatriptan benzoate
- 26. Zolmitriptan
- 27. Metoclopramide
- 28. Chlorpromazine
- 29. Valproate
- 30. Ketorolac

Other Treatments

- 1. Nerve blocks
- 2. Trigger point injections
- 3. Injections of botulinum toxin
- 4. Inpatient treatment

Nonpharmacologic Treatments

- 1. Biofeedback
- 2. Stress management
- 3. Cognitive behavioral therapy

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guidelines presented in this monograph represent the consensus of an advisory panel of practitioners chosen by the National Headache Foundation (NHF) for their expertise. In addition to incorporating the US Headache Consortium's recommendations, their conclusions reflect clinical experience and the most recent medical literature.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Chronic Daily Headache (CDH)

Diagnosis and Treatment

The approach to the patient with CDH is straightforward. First, a diagnosis must be made. There are several diagnostic categories of CDH, including:

- Constant (last all day)
- Daily but not constant (lasting for minutes or hours)
- Secondary (due to an underlying medical illness)
- Primary (not related to structural or systemic illness)

Secondary causes of CDH (see table below titled "Secondary Causes of CDH") must be considered and ruled out. Once a primary form of CDH is diagnosed (see table below titled "Primary Types of CDH"), it is important to educate patients and involve them in the treatment plan. Early consultation with a headache specialist is appropriate.

Secondary Causes of CDH

- Post-traumatic (may mimic any primary headache)
- Cervicogenic (especially C2, C3 upper root entrapment)
- Temporomandibular joint syndrome
- Sinus disease
- Arteriovenous malformation
- Arteritis (including giant cell arteritis)
- Subdural hematoma
- Vascular dissection
- Neoplasm
- Infections
- Intracranial hypertension
- Intracranial hypotension

Note: All diagnoses may be confounded by medication overuse.

Primary Types of CDH

- Chronic tension-type headache
- Chronic migraine (formerly known as transformed migraine with or without analgesic rebound)
- New daily persistent headache
- Chronic cluster headache
- Hemicrania continua
- Chronic paroxysmal hemicrania
- Hypnic headache
- Idiopathic stabbing headache
- SUNCT (short-lasting, unilateral neuralgiform headaches with conjunctival injection and tearing)

Primary Types of CDH

• Cranial neuralgias (e.g., trigeminal neuralgia)

Medication Overuse

Treating patients with CDH can be challenging, particularly if the headaches are complicated by medication overuse. Often, patients may not realize that excessive or frequent self-treatment may actually worsen their condition. Continued overuse of immediate-relief medications, particularly in headache-prone patients, may result in refractoriness to treatment (prophylactic medications may not work), perpetuation of the headaches, and a transformation from a pattern of intermittent migraine to one of CDH. The diagnosis of CDH may be obscured by medication-overuse headache. A 2-month period is required after cessation of medication overuse to establish the diagnosis with certainty.

Virtually any medication used more than 2 to 3 days per week may cause these phenomena, including off-the-shelf remedies such as acetaminophen and prescription agents such as the triptans. Combination products containing caffeine and butalbital may be especially likely to generate "analgesic rebound," whereas drugs with a longer duration of action (i.e., a longer half-life) may be less likely to do so. Clinicians should be careful to screen CDH patients for medication overuse and should make it a point to counsel their patients about the risks of analgesic overuse and rebound headache.

Confounding overuse of medications must be stopped. Many drugs can be abruptly stopped, although measures must be taken to cover the withdrawal headache that will likely ensue. Sometimes a steroid taper and an antiemetic will suffice. Drugs such as narcotics, butalbital, and benzodiazepines in general should not be stopped abruptly but rather should be tapered. The use of clonidine for opioid withdrawal or the temporary substitution of phenobarbital for butalbital to avoid seizures or other serious withdrawal symptoms may be instituted to moderate withdrawal. Intravenous dihydroergotamine (DHE) given over several days may provide sufficient relief of the underlying headache to allow the patient to discontinue the offending acute medications.

Acute Treatment

Many patients can be helped through outpatient therapy, and the diagnosis will determine the most appropriate choice of acute treatment (see table below). However, limits on acute medication use of 2 to 3 days per week need to be instituted, along with avoidance of the agent that was being overused. For example, if the patient is experiencing chronic migraine, antimigraine agents such as the triptans, nonsteroidal anti-inflammatory drugs (NSAIDs), and DHE can be effective, provided the patient has not previously overused any symptomatic medication. Table 7.5 of the original guideline document provides guidelines for treating intractable migraine, or migraine lasting for more than 24 hours in spite of treatment. Chronic tension-type headache (CTTH) can be effectively managed with analgesics. For hemicrania continua and chronic paroxysmal hemicrania, prompt resolution of the headache with a trial of indomethacin 50 mg 3 times a day for 48 hours will establish the diagnosis. As with other forms of CDH,

secondary forms need to be considered, and confounding medication overuse needs to be addressed. Most patients will have a dramatic response to indomethacin and a lesser response to other NSAIDs.

Medications Studied in CDH

- Acetazolamide
- Amitriptyline
- Botulinum toxin type A
- Divalproex sodium
- Doxepin
- Fluoxetine
- Indomethacin
- Nefazodone
- Phenelzine
- Tizanidine
- Topiramate

Regardless of past medication use, drugs used for the acute treatment of CDH should be strictly limited to reduce the chance of complicating treatment. If a patient regularly seeks medications on a more frequent basis than guidelines suggest (see table below), reevaluation of the diagnosis and assessment for preventive treatment may be indicated.

Limitation Guidelines for Use of Abortive Therapies in Headache	
SUBSTANCE/MEDICATION	GUIDELINES
	Treatment day = 24 hours
Caffeine (often found in combination over-	2 treatment days/week. Both dosage and frequency o
the-counter [OTC] and prescription	affect development of withdrawal headaches or symp
medications)	Caffeine from beverage consumption also contributes total dosage.
Codeine	2 treatment days/week
Oxycodone	2 treatment days/week
Butalbital	2 treatment days/week
Propoxyphene	2 treatment days/week
Butorphanol	2 treatment days/week
Ergotamine tartrate: oral (p.o.), rectal, sublingual	8 treatment days/month or 2 treatment days/week (c less)
Almotriptan	8 treatment days/month or 2 treatment days/week
Eletriptan	8 treatment days/month or 2 treatment days/week
Frovatriptan	8 treatment days/month or 2 treatment days/week
Sumatriptan succinate: subcutaneous (SQ), p.o., rapid-release tablet, intranasal	8 treatment days/month or 2 treatment days/week
Naratriptan hydrochloride: p.o.	8 treatment days/month or 2 treatment days/week
Rizatriptan benzoate: p.o. and orally disintegrating tablet	8 treatment days/month or 2 treatment days/week
Zolmitriptan: p.o., oral disintegrating tablet, intranasal	8 treatment days/month or 2 treatment days/week

Note: In general, the use of opiates/opioids for the symptomatic management of pain should be lir to instances in which acute abortive therapy has failed or is contraindicated. Opioids, as a class, sho

Limitation Guidelines for Use of Abortive Therapies in Headache	
SUBSTANCE/MEDICATION	GUIDELINES
	Treatment day = 24 hours

be limited to no more than 2 days/week, regardless of which agent is used. However, when they are used, they should be administered at a sufficient dose to provide adequate analgesia.

Preventive Treatment

Patients with very frequent headaches should be treated primarily with preventive medications (see National Headache Foundation [NHF] guidelines on "Preventive Treatment of Migraine") to reduce the frequency, severity, and duration of the headaches. Choices for prevention of CTTH, new daily persistent headache, and chronic migraine are best made on the basis of concomitant or comorbid conditions. Medications should generally be started at a low dose, followed by gradual increases in dose until efficacy is achieved, side effects become intolerable, or the ceiling dose is reached. Nonpharmacologic therapies such as biofeedback, stress management, and cognitive behavioral therapy should also be considered. Monotherapy is the preferred approach, as the prescription of copharmaceutical treatments should be reserved for physicians specializing in the treatment of headache. Specific therapies exist for chronic paroxysmal hemicrania and hemicrania continua (e.g., indomethacin). The same is true for hypnic headaches, cranial neuralgias, and chronic cluster headache.

Psychiatric comorbidities such as anxiety and depression are common and need to be considered. All forms of psychiatric comorbidities may be complicated by medication overuse, which may limit the effectiveness of preventive medications; therefore, medication overuse also needs to be addressed. It is also critical to communicate realistic expectations to patients, as it may take up to 6 weeks or more for preventive medications to become fully effective.

Inpatient Treatment

For patients who fail to respond to outpatient treatment, or whose conditions are too complicated for outpatient detoxification and treatment, inpatient treatment may be considered. Outpatient treatment is best conducted in a setting with experienced practitioners who can take a multidisciplinary approach to the medical issues. The mainstay of the approach is to resolve medication overuse, cover the withdrawal headache likely to occur in the first several days after admission, address comorbid and coexistent conditions, and institute preventive therapy. Intravenous regimens that have been used for intractable headache include repetitive metoclopramide and DHE, neuroleptics (such as chlorpromazine), valproate, or ketorolac. More information can be found in the NHF guidelines on "Inpatient Headache Treatment."

Other Treatments

Less commonly used treatment modalities for CDH may be best employed by practitioners who are headache experts. These modalities include nerve blocks (e.g., occipital nerve blocks), trigger point injections, and injections of botulinum toxin. The use of botulinum toxin is controversial, with anecdotal reports of efficacy in some patients with CDH. In some cases of "cervicogenic headache,"

especially in some cases of post-traumatic headache, some experts advocate procedures directed against the C2 and/or C3 nerve roots, with deep computed tomography-guided blocks said to be diagnostic. Ultimately, the best approach to CDH is to make a clear diagnosis early and to institute treatment early, before disability becomes manifest and the situation becomes complicated by medication overuse and psychiatric issues. Early referral of the patient to a practitioner skilled in the diagnosis and treatment of headache is essential. Patients with refractory headache may need to be admitted for inpatient treatment.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

In addition to incorporating the US Headache Consortium's recommendations, the conclusions reflect clinical experience and the most recent medical literature.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and management of chronic daily headache (CDH)

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Drug therapy is constantly evolving as new research, clinical trials, case reports, and opinions are published. Many of the drugs recommended in these guidelines are not approved by the US Food and Drug Administration (FDA) for treatment of headache, nor are they necessarily the same as those therapies recommended by the manufacturer for labeled indications. Their use in headache, however, may be supported by the scientific literature and by the authors' clinical experiences. While efforts have been made to ensure accuracy, the authors and publisher do not assume responsibility for the consistent updating of available information for these guidelines, nor for any errors or omissions, nor for any consequences thereof. The onus is on the practitioner to evaluate recommendations in light of the clinical condition of the patient and recent medical literature. The authors advise the practitioner to consult other sources, especially the manufacturers' warnings and precautions, before prescribing any drug with which they are

unfamiliar. Practitioners are also advised that while these guidelines will address the needs of many patients, there will be circumstances calling for exceptions to these recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Foreign Language Translations
Patient Resources
Slide Presentation

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Mathew N, Ward T. Treatment of primary headache: chronic daily headache. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 73-80. [4 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004

GUI DELI NE DEVELOPER(S)

National Headache Foundation - Private Nonprofit Organization

SOURCE(S) OF FUNDING

National Headache Foundation

GUI DELI NE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Ninan Mathew, MD, and Thomas Ward, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUI DELI NE AVAI LABI LI TY

Electronic copies: None available

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- The complete headache chart. Chicago (IL): National Headache Foundation (NHF); 2 p. Electronic copies available in Portable Document Format (PDF) from the National Headache Foundation Web site
- National Headache Foundation fact sheet. Chicago (IL): National Headache Foundation (NHF); 2004 Oct. 2 p. Electronic copies available in Portable Document Format (PDF) from the <u>National Headache Foundation Web site</u>.

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org

PATIENT RESOURCES

The National Headache Foundation (NHF) has created a variety of educational resources for patients, including informative brochures, a patient diary for migraines, Power Point presentations, and patient guides; many of these resources are available in both Spanish and English. Some of these items are available as print copies for purchase through the NHF online store. Electronic versions of other resources are available through the consumer education section of the NHF Web site.

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on April 11, 2005. The information was verified by the guideline developer on April 26, 2005. This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs).

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